Clariant Corporation

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Charlotte, NC 28205
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SEP 19 2005

Via FedEx 7906 4774 2166

September 16, 2005

Kimberly Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

RE: Addenda to Conceptual Exposure Model Report (August 2004 Revision) and Exposure and Screening-Level Risk Assessment Report (April 11, 2005 Revision), Red Pigment Project

Dear Ms. Tisa:

Enclosed are two documents which amend and supplement Clariant's two key prior submittals of risk assessment reports regarding the contaminated red pigment incident. These documents incorporate new data regarding pigment contaminant concentration (as determined by an independent, third-party laboratory) which we discussed in our conference call on June 16, 2005, as well as new information regarding Tier II customers which was communicated to you via my e-mail of July 8, 2005. Clariant had requested instructions regarding how this new information should be formally submitted to EPA, but in the absence of such guidance, has decided to submit the information in the form of non-CBI addenda to the prior risk assessment reports. We trust this is an acceptable method, but if not, please let me know. If deemed necessary, a CBI version of the addenda to the August 2004 report can be created and submitted to the Agency.

In summary, the conclusions of the prior risk assessments are not significantly affected by the inclusion of the new data and customer information.

Also, you will recall from our conversation on June 16 that Versar requested additional information and clarification from Clariant's consultant, BBL Sciences, regarding the risk assessment calculations contained in the reports. Dr. John Schell of BBL supplied this information to you via an e-mail dated July 11, 2005. To date, we have not received any feedback on BBL's response.

Clariant

We look forward to the Agency's response to these and prior submittals. If you have any questions or require additional information, I can be reached at 704-331-7104 or via email at mike.teague@clariant.com

Sincerely,

CLARIANT CORPORATION

Michael A. Teague, Ph.D.
Vice President / ESHA

Enclosures

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul

ADDENDUM TO REPORT:

CONCEPTUAL EXPOSURE MODEL AND PRELIMINARY ASSESSMENT FOR END USERS OF PIGMENTS RED 144 AND 214

AUGUST 2004 REVISION

Prepared for Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205

Prepared by BBL Sciences

September 16, 2005

THIS DOCUMENT IS COMPANY SANITIZED. NO TSCA CONFIDENTIAL BUSINESS INFORMATION IS CONTAINED IN THIS DOCUMENT

Table of Contents

1. New Information

Since the publication of the original Conceptual Exposure Model (CEM) report in August 2004, new information on product concentration and use was obtained by Clariant Corporation (Clariant). The purpose of the current Addendum is to present that information and to make changes to the results and conclusions of the original report. This Addendum incorporates the abridged components of the CEM report to facilitate the discussion of changes triggered by the new data.

2. Background

To assess the likelihood for exposure and risk to human receptors associated with the potential release from the non-compliant pigment, the Clariant Corporation developed a CEM. A CEM forms the basis of identifying exposure scenarios that must be evaluated in a risk assessment context (USEPA, 2004). Initially developed from existing information and relevant data, a CEM characterizes all potential or suspected sources of a chemical or chemicals of concern, types and concentrations of chemicals detected in primary products, transportation and distribution of primary products to secondary users, potentially affected media, and potential exposure pathways, including potential receptors (USEPA, 2002; USEPA, 2004).

3. Scope of the Assessment

The CEM focused on polychlorinated biphenyls (PCBs) from Pigments Red 144 and 214. The exposure assessment used the existing information on the identified sources of chemicals of concern, concentrations detected in primary and secondary products (pigment and end use products), transportation and distribution of products to secondary users, potentially affected media, potential exposure pathways, and human receptors. The primary receptors in the analysis were the production workers and users of end products containing the pigments. Tier I users were defined as those customers who received pigment directly from Clariant's pigment manufacturing plant. These Tier I users incorporate the pigment into an intermediate form that is then used downstream by the manufacturers of end products. Tier II users were defined as those customers who receive pigment from a Tier I user, in an intermediate form such as a masterbatch, to help color an end product. The production workers at Clariant's pigment manufacturing facility and Clariant's Masterbatch facilities (Tier I user) were not part of that assessment because previous human health risk evaluations led to the conclusion that Clariant's workers' exposure and risk are very low in each of these manufacturing operations. In the development of an overall CEM, all users have been coded due to confidentiality issues; the company-specific identifier will be used throughout the CEM in order to minimize the claims of Toxic Substances Control Act (TSCA) Confidential Business Information.

4. Analytical Approach

4.1 Exposure Route and Pathway Dendograms

Clariant sales records (updated and revised through September 2005) were used to identify the type and quantity of pigment sold (after subtracting any returns) to each customer. The results from the customer survey conducted by Clariant were used to identify the type of end products incorporating the pigments. Clariant internal analytical results for each commercial lot were used to calculate the total mass and concentrations of total PCBs (tPCBs) in those end products. The extracted information was organized into comprehensive flow chart dendograms tracing the route of pigment transport from Clariant to Tier I users, and subsequently on to Tier II users and end product users. The charts were constructed using the U.S. Environmental Protection Agency's (USEPA's) graphics building tool, *Site Conceptual Exposure Model Builder* (http://homer.ornl.gov/oepa/programs/scem.cfm), and were included in the original report. For each Tier I user, a separate dendogram of exposure pathways associated with production activities was constructed. Those pathways included releases to air, wastewater treatment, solid waste storage, product storage, spills, stormwater runoff, and end product disposal and subsequent transport into soil, groundwater, and, surface water. The identified routes of potential uptake by human receptors included inhalation; dermal absorption; and ingestion of dust, as well as of crops, livestock, and wild game that may have had accumulated tPCBs originating from the pigments as a result of releases to the environment. For each Tier II user, a flow chart of pathways and routes associated with the end product use was developed in addition to a dendogram of exposure routes and pathways associated with production activities. The end product use typically was concerned with potential off gassing of tPCBs into air and subsequent inhalation, production of surface dusts and the potential for dermal absorption and ingestion of the end product. All possible exposure route and pathway dendograms of pigment-borne tPCBs were combined into one document available only in hardcopy format (Appendix I of the original document).

4.2 Database Manipulations

4.2.1 Pooling of End Product Manufacturers into Groups

In many instances, Tier II users produced the same or similar items, and those products often had similar tPCB concentrations. In some cases, different Tier II users were incorporating the same or similar raw materials supplied by the same Tier I manufacturer. Therefore, one representative producer with the maximum PCB concentration in the end product was chosen for the purpose of delineating and evaluating the exposure

pathways associated with a given product. Table 1 presents these groupings. In 2005, new information identified an additional use: industrial conveyor belts. This use was added to the original list of product types.

The major groups of Tier II users by product type were as follows:

a. Fiber and carpet yarn producers (Tier II users A.1 to A.16);

b. Users of external labeling on IV bags (Tier II users B.1 to B.6);

c. Producers of tubing for air, fuel, oil, and refrigerant (Tier II users C.1 to C.3);

d. Snow flap makers (Tier II users D.1 and D.2);

e. Makers of automotive electrical connectors and spacers (Tier II users E.1 and E.2);

f. Tool producers (Tier II users F.1 to F.3);

g. Makers of accessories (Tier II users G.1 to G.4);

h. Makers of injection-molded doghouses (Tier II user H.1);

i. Producers of packing film, tape, and food trays (Tier II users I.1 and I.2);

j. Makers of textiles (Tier II users J.1 and J.2);

k. Makers of gaskets (Tier II user K.1);

l. Producers of displays (Tier II user L.1),

m. Manufacturers of syringe disposal containers (Tier II user M.1);

n. Makers of furniture and flooring (Tier II users N.1 to N.3);

o. Makers of countertops (Tier II users O.1 to O.10);

p. Makers of tubs and spas (Tier II users P.1 to P.57);

q. Unknown end users:

   -Q.1 (went out of business),
   -Q.2 (recycles plastics into unknown products), and
   -Q.3 (refused to provide information);

r. Glue producers (Tier II user R.1); and

s. Makers of industrial conveyor belts (Tier II user S.1).

4.2.2 Occupational Criteria and Exposure Potential

The pooled end product groups of Tier II users were subjected to an iterative logical test utilizing two evaluation criteria: information on potential for exposure (Criterion I) and the maximum concentration of tPCBs in end product (Criterion II). The decision whether a given group of end products may lead to a significant quantifiable exposure to human receptors was subsequently declared as a scenario of potential concern. This designation necessitated a more detailed exposure and risk assessment based on satisfaction of Criterion I and Criteria IIa or IIb (see Section 4.2.2.2). If any of the criteria were rejected, no further risk analysis was necessary because either there is no potential for exposure or the potential exposure is quantitatively insignificant. The following sections define the selection criteria. Table 1 provides a summary of the screening analysis for the updated information.

4.2.2.1 Criterion I

This criterion was a professional judgment as to whether the intended use of the product leads to a direct human exposure based on quantities of pigment sold and the duration and frequency of exposure.

4.2.2.2 Criterion II

Criterion II was sub-divided into two components, depending on the anticipated exposure route. Selection Criterion IIa was applied where dermal exposure was most likely the only contact to occur, and Selection Criterion IIb was applied where an ingestion, inhalation, and dermal contact was plausible. The specifics of the criteria include:

a. For dermal exposure scenarios, a product concentration-based limit of 10 parts per million (ppm) was used. The 10 ppm value is the cleanup level for bulk PCB remediation waste in "high occupancy areas" where a barrier is in place to "minimize human exposure," as defined in the *Disposal of Polychlorinated Biphenyls (PCBs); Final Rule* (Federal Regulations [Fed. Reg.]: June 29, 1998 [Vol. 63(124)]). Typically, the categories of products that would be tested against this criterion are those handled only by adults, where the pigments are impregnated into a nonporous material (e.g., plastics), and there is no potential for the internal route of uptake. Because of the nature of this material, individuals exposed to any PCBs contained in these products would have limited direct access (i.e., low bioavailability and bioaccessibility). The value of 10 ppm was considered conservative since it is lower than the "low occupancy area" cleanup level (i.e., 25 ppm) but considers the low bioavailability of the tPCBs in these materials that are not ingestible and do not generate significant levels of dust.

b. For ingestion and inhalation scenarios, a product concentration-based limit of 1 ppm was used. The 1 ppm tPCBs corresponds to the cleanup level for the "high occupancy area" soil level described in the PCB Disposal Rule (Fed. Reg.: June 29, 1998 [Vol. 63(124)]) and was considered a conservative benchmark for evaluating exposures from these types of scenarios. This criterion was applied where the normal handling and use of a given product can lead to ingestion or inhalation of the product, especially in those situations where dust is generated from the product.

5. Results

The exposure model analysis revealed that there are 119 Tier II users who received tPCB-containing pigment and whose products range from carpet and fabric materials to various injection-molded items used by industrial and non-industrial users. The concentrations of tPCBs in those products range from a low of 0.0008 ppm in accessories (Group G) to a high of 14.1 ppm in carpet (Group A). These observations (based on revised data) are different from those reported in the original report, where the range spanned from 0.04 ppm to 4.1 ppm. In Table 1, the updated values are shown in red. The application of the exposure pathways and routes selection criteria revealed that only 13 Tier II users may be associated with potential exposure. These Tier II users were placed in two exposure scenarios: 1) fiber and carpet yarn producers (Group A); and 2) packing film, tape, and packing trays (Group J). Both scenarios were identified as potentially significant based on satisfying both Criteria I and IIb. User A.13 was the surrogate (with the highest PCB concentration) for fiber and carpet yarn scenario, and user I.1 was the surrogate for packing film, tape, and packing trays scenario. The new use, conveyor belt production, was not associated with potential exposure.

Table 1

September 2005 Revised Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Tier II User	Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with HHRA?
				A (10 ppm)	B (1 ppm)	
A. Fiber and Carpet Yarn						
CONFIDENTIAL	A.1	3.1	Y	NA	Y	Y
CONFIDENTIAL	A.2	1.6	Y	NA	Y	Y
CONFIDENTIAL	A.3	NR	?	?	?	?
CONFIDENTIAL	A.4	NR	?	?	?	?
CONFIDENTIAL	A.5	3.1	Y	NA	Y	Y
CONFIDENTIAL	A.6	2.4	Y	NA	Y	Y
CONFIDENTIAL	A.7	2.6	Y	NA	Y	Y
CONFIDENTIAL	A.8	3.1	Y	NA	Y	Y
CONFIDENTIAL	A.9	5.5	Y	NA	Y	Y
CONFIDENTIAL	A.10	4.1	Y	NA	Y	Y
CONFIDENTIAL	A.11	NR	Y	NA	?	?
CONFIDENTIAL	A.12	4.1	Y	NA	Y	Y
CONFIDENTIAL	A.13	14.1	Y	NA	Y	Y
CONFIDENTIAL	A.14	4.1	Y	NA	Y	Y
CONFIDENTIAL	A.15	3.4	Y	NA	Y	Y
CONFIDENTIAL	A.16	NR	?	?	?	?
B. Intravenous Bag Labels						
CONFIDENTIAL	B.1	<10	Y	N	NA	N
CONFIDENTIAL	B.2	<10	Y	N	NA	N
CONFIDENTIAL	B.3	<10	Y	N	NA	N
CONFIDENTIAL	B.4	<10	Y	N	NA	N
CONFIDENTIAL	B.5	<10	Y	N	NA	N
CONFIDENTIAL	B.6	<10	Y	N	NA	N
C. Air, Fuel, Oil, and Refrigerant Tubing						
CONFIDENTIAL	C.1	1.0	Y	N	NA	N
CONFIDENTIAL	C.2	0.3	Y	N	NA	N
CONFIDENTIAL	C.3	3.9	Y	N	NA	N
D. Snow Flaps						
CONFIDENTIAL	D.1	8.2	Y	N	NA	N
CONFIDENTIAL	D.2	0.1	Y	N	NA	N
E. Automotive Electrical Connectors and Spacers						
CONFIDENTIAL	E.1	1.5	Y	N	NA	N
CONFIDENTIAL	E.2	1.5	Y	N	NA	N
F. Tools						
CONFIDENTIAL	F.1	0.52	Y	N	NA	N
CONFIDENTIAL	F.2	1.5	Y	N	NA	N
CONFIDENTIAL	F.3	2.5	Y	N	NA	N
G. Accessories						
CONFIDENTIAL	G.1	0.00076	Y	N	NA	N
CONFIDENTIAL	G.2	0.5	Y	N	NA	N
CONFIDENTIAL	G.3	1.0	Y	N	NA	N
CONFIDENTIAL	G.4	1.2	Y	N	NA	N

Table 1
September 2005 Revised Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Tier II User	Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with Risk Assessment?
				A (10 ppm)	B (1 ppm)	
H. Injection Molded Doghouses						
CONFIDENTIAL	H.1	0.15	Y	N	NA	N
I. Packing Film, Tape, and Food Trays						
CONFIDENTIAL	I.1	2.4	Y	NA	Y	Y
CONFIDENTIAL	I.2	0.34	Y	NA	N	N
J. Textiles						
CONFIDENTIAL	J.1	NR	Y	NA	?	?
CONFIDENTIAL	J.2	NR	N[5]	NA	?	N
K. Gaskets						
CONFIDENTIAL	K.1	0.52	Y	N	NA	N
L. Displays						
CONFIDENTIAL	L.1	0.52	Y	N	NA	N
M. Syringe Containers						
CONFIDENTIAL	M.1	0.08	Y	N	NA	N
N. Furniture and Flooring						
CONFIDENTIAL	N.1	NR	Y	NA	?	?
CONFIDENTIAL	N.2	NR	Y	NA	?	?
CONFIDENTIAL	N.3	NR	Y	NA	?	?
O. Countertops						
CONFIDENTIAL	O.1	0.1	Y	N	NA	N
CONFIDENTIAL	O.2	0.1	Y	N	NA	N
CONFIDENTIAL	O.3	0.1	Y	N	NA	N
CONFIDENTIAL	O.4	0.1	Y	N	NA	N
CONFIDENTIAL	O.5	0.1	Y	N	NA	N
CONFIDENTIAL	O.6	0.1	Y	N	NA	N
CONFIDENTIAL	O.7	0.1	Y	N	NA	N
CONFIDENTIAL	O.8	0.1	Y	N	NA	N
CONFIDENTIAL	O.9	0.1	Y	N	NA	N
CONFIDENTIAL	O.10	0.1	Y	N	NA	N
P. Tubs and Spas						
CONFIDENTIAL	P.1	0.1	Y	N	NA	N
CONFIDENTIAL	P.2	0.1	Y	N	NA	N
CONFIDENTIAL	P.3	0.3	Y	N	NA	N
CONFIDENTIAL	P.4	0.1	Y	N	NA	N
CONFIDENTIAL	P.5	0.1	Y	N	NA	N
CONFIDENTIAL	P.6	0.1	Y	N	NA	N
CONFIDENTIAL	P.7	0.1	Y	N	NA	N
CONFIDENTIAL	P.8	0.1	Y	N	NA	N
CONFIDENTIAL	P.9	0.1	Y	N	NA	N
CONFIDENTIAL	P.10	0.1	Y	N	NA	N
CONFIDENTIAL	P.11	0.1	Y	N	NA	N
CONFIDENTIAL	P.12	0.1	Y	N	NA	N
CONFIDENTIAL	P.13	0.1	Y	N	NA	N

Table 1

September 2005 Revised Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Tier II User	Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with Risk Assessment?
				A (10 ppm)	B (1 ppm)	
P. Tubs and Spas (Cont)						
CONFIDENTIAL	P.14	0.1	Y	N	NA	N
CONFIDENTIAL	P.15	0.1	Y	N	NA	N
CONFIDENTIAL	P.16	0.1	Y	N	NA	N
CONFIDENTIAL	P.17	0.1	Y	N	NA	N
CONFIDENTIAL	P.18	0.1	Y	N	NA	N
CONFIDENTIAL	P.19	0.1	Y	N	NA	N
CONFIDENTIAL	P.20	0.1	Y	N	NA	N
CONFIDENTIAL	P.21	0.1	Y	N	NA	N
CONFIDENTIAL	P.22	0.1	Y	N	NA	N
CONFIDENTIAL	P.23	0.1	Y	N	NA	N
CONFIDENTIAL	P.24	0.1	Y	N	NA	N
CONFIDENTIAL	P.25	0.1	Y	N	NA	N
CONFIDENTIAL	P.26	0.3	Y	N	NA	N
CONFIDENTIAL	P.27	0.1	Y	N	NA	N
CONFIDENTIAL	P.28	0.1	Y	N	NA	N
CONFIDENTIAL	P.29	0.1	Y	N	NA	N
CONFIDENTIAL	P.30	0.1	Y	N	NA	N
CONFIDENTIAL	P.31	0.1	Y	N	NA	N
CONFIDENTIAL	P.32	0.1	Y	N	NA	N
CONFIDENTIAL	P.33	0.1	Y	N	NA	N
CONFIDENTIAL	P.34	0.1	Y	N	NA	N
CONFIDENTIAL	P.35	0.1	Y	N	NA	N
CONFIDENTIAL	P.36	0.3	Y	N	NA	N
CONFIDENTIAL	P.37	0.1	Y	N	NA	N
CONFIDENTIAL	P.38	0.1	Y	N	NA	N
CONFIDENTIAL	P.39	0.1	Y	N	NA	N
CONFIDENTIAL	P.40	0.1	Y	N	NA	N
CONFIDENTIAL	P.41	0.1	Y	N	NA	N
CONFIDENTIAL	P.42	0.1	Y	N	NA	N
CONFIDENTIAL	P.43	0.1	Y	N	NA	N
CONFIDENTIAL	P.44	0.1	Y	N	NA	N
CONFIDENTIAL	P.45	0.1	Y	N	NA	N
CONFIDENTIAL	P.46	0.1	Y	N	NA	N
CONFIDENTIAL	P.47	0.1	Y	N	NA	N
CONFIDENTIAL	P.48	0.1	Y	N	NA	N
CONFIDENTIAL	P.49	0.1	Y	N	NA	N
CONFIDENTIAL	P.50	0.1	Y	N	NA	N
CONFIDENTIAL	P.51	0.1	Y	N	NA	N
CONFIDENTIAL	P.52	0.1	Y	N	NA	N
CONFIDENTIAL	P.53	0.1	Y	N	NA	N
CONFIDENTIAL	P.54	0.1	Y	N	NA	N
CONFIDENTIAL	P.55	0.1	Y	N	NA	N
CONFIDENTIAL	P.56	0.1	Y	N	NA	N
CONFIDENTIAL	P.57	0.1	Y	N	NA	N

Table 1

September 2005 Revised Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Tier II User	Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with Risk Assessment?
				A (10 ppm)	B (1 ppm)	
Q. Unknown						
CONFIDENTIAL	Q.1	0.52	?	?	?	?
CONFIDENTIAL	Q.2	NR	?	?	?	?
CONFIDENTIAL	Q.3	NR	?	?	?	?
R. Glue						
CONFIDENTIAL	R.1	0.01	Y	N	NA	N
S. Industrial Conveyor Belts						
CONFIDENTIAL	S.1	0.8	Y	N	NA	N

September 2005 updated information in red font

NR-Not reported in database; NA-Not applicable; HHRA-Human health risk assessment

[1]Out of business, [2]Recycling of plastics into unknown products, [3]Client refused to provide information

?-Assessment not possible due to data gap

ADDENDUM TO REPORT:

EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR CARPET FIBER AND FOOD WRAP SCENARIOS ASSOCIATED WITH PIGMENTS RED 144/214

APRIL 11, 2005 REVISION

Prepared for Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205

Prepared by BBL Sciences

September 16, 2005

Table of Contents

1. Introduction

The April 11, 2005 report titled "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" contained a screening-level risk assessment for children potentially exposed to carpet fiber and for the general population potentially exposed to food wrap. The goal of that assessment was to calculate acceptable, risk-based levels of total polychlorinated biphenyls (tPCBs) in carpet yarn and fiber using cancer and non-cancer risk/hazard thresholds and children-specific exposure factors. For the food wrap scenario, the goal was to determine whether the maximum concentration of tPCBs contained in the tinted food wrap would lead to elevated hazard or risk. Recently (September 2005), new observations were added to input data. Namely, the maximum carpet concentration was revised downward from 16.4 ppm to 14.1 ppm based on the re-analysis of the maximum concentration of PCB in pigment sent to carpet manufacturers, and the maximum food wrap concentration was revised upward from 0.06 to 0.34 ppm, and packing tape from 1.1 to 2.4 ppm based on new analytical data. The objective of the current Addendum is to update the April 11 report with the new data. This Addendum incorporates the abridged components of the original report to facilitate the discussion of the effects that new data may have on the outcome of the risk assessment.

2. Carpet Scenario

As indicated in the original report, the primary receptors for this analysis were young children (1 to 10 years old), who may be exposed to tPCBs in the pigments via daily activities on carpeted surfaces. The extent of contact between children and carpet-borne constituents of interest was calculated via an exposure model. This model considered ingestion, dermal uptake, and inhalation exposure routes. The model and the associated input parameters are briefly discussed below.

2.1 Exposure Model

2.1.1 Non-Cancer Hazard

The combined exposures calculation model for non-cancer hazard was as follows:

$$CNC_{Carpet} = \frac{THQ \cdot BW \cdot AT_{nc}}{ED \cdot EF\left[\left(\frac{1}{RfD} \cdot \frac{IR \cdot BioAF}{10^6 mg/kg}\right) + \left(\frac{1}{RfD} \cdot \frac{SA \cdot AF \cdot DERM}{10^6 mg/kg}\right) + \left(\frac{1}{RfD} \cdot IHR \cdot \frac{1}{VF} \cdot RF\right)\right]}$$

Equation 1

where,

CNC_{Carpet} – risk-based concentration in carpet fiber associated with hazard quotient of 1 (mg/kg);
THQ – target hazard quotient (unitless);
BW – body weight (kg);
RfD – non-cancer reference dose (mg/kg BW/day);
AT_{nc} – non-cancer averaging time (days);
ED – exposure duration (yrs);
EF – exposure frequency (days/yr);
IR – dust ingestion rate (mg/day);
$BioAF$ – bioavailability factor for ingestion (unitless);
SA – contact skin surface area (cm^2/day);
AF – dust adherence factor (mg/cm^2);
$DERM$ – dermal absorption factor (unitless);
IHR – inhalation rate (m^3/day);
VF – volatilization factor (m^3/kg); and
RF – retention factor (unitless).

The VF used in the above equation was calculated via a set of concentration relationships derived experimentally for an enclosed chamber containing a carpet sample impregnated with a substance of interest (Bennet and Furtaw, 2004 citing Won et al., 2000). The relationships describing carpet surface to air partitioning (K_{SA}) were as follows:

$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82-0.62\log VP}$$ **Equation 2**

where,

$$\frac{k_s}{k_d} = \frac{M}{C_g}$$ **Equation 3**

substituting Equation 3 into Equation 2 and solving for M yields

$$M = (d_w \cdot 10^{3.82-0.62\log VP} \cdot C_g)$$ **Equation 4**

where,

k_s – adsorption coefficient (m/hr);

k_d – desorption coefficient (m/hr);

d_w – carpet thickness (m);

VP – vapor pressure (Pa);

C_g – acceptable concentration of PCBs in air from Equation 1 and 9 (mg/m^3); and

M – mass of PCBs per area of carpet (mg/m^2).

To express M on carpet weight basis (M_{cw}; mg/kg), this parameter can be divided by carpet face weight (FW; kg/m^2) such that

$$M_{cw} = \frac{(d_w \cdot 10^{3.82-0.62\log VP} \cdot C_g)}{FW}$$ **Equation 5**

Furthermore, in realistic conditions of a normal house, ventilation is provided to maintain proper air quality. Therefore, the M_{cw} term must allow for a dilution factor (AE; unitless) to avert modeling unrealistically high concentrations. Thus, Equation 5 is modified to

$$M_{cw} = \frac{d_w \cdot 10^{3.82-0.62\log VP} \cdot C_g \cdot AE}{FW}$$ **Equation 6**

The VF (m^3/kg) was derived by dividing M_{cw} by the air concentration term C_g (Equation 7). The VF was inserted into Equation 1 to calculate an acceptable carpet concentration attributable to tPCB volatilization.

$$VF = \frac{M_{cw}}{C_g} = \frac{(d_w \cdot 10^{3.82-0.62\log VP} \cdot AE)}{FW}$$ **Equation 7**

Given that C_g is calculated in Equation 1 and 9 using the inhalation exposure assumptions, VF was inserted into these equations to derive an acceptable concentration in carpet fiber (M_{cw}; mg/kg):

$$VF^*C_g = M_{cw}$$ **Equation 8**

2.1.2 Cancer Risk

The combined exposures back-calculation model for cancer risk is as follows:

$$CC_{Carpet} = \frac{TR \cdot BW \cdot AT_c}{ED \cdot EF\left[\left(\frac{CSF \cdot IR \cdot BioAF}{10^6 mg/kg}\right) + \left(\frac{CSF \cdot SA \cdot AF \cdot DERM}{10^6 mg/kg}\right) + \left(CSF \cdot IHR \cdot \frac{1}{VF} \cdot RF\right)\right]}$$ **Equation 9**

where,

CC_{Carpet} – risk-based concentration in carpet associated with 1 x 10^{-6} cancer risk (mg/kg);
TR – target cancer risk;
BW – body weight (kg);
CSF – cancer slope factor (mg/kg BW/day)$^{-1}$;
AT_c – cancer averaging time (days);
ED – exposure duration (yrs);
EF – exposure frequency (days/yr);
IR – dust ingestion rate (mg/day);
BioAF – bioavailability factor for ingestion (unitless);
SA – contact skin surface area (cm^2/day);
AF – dust adherence factor (mg/cm^2);
IHR – inhalation rate (m^3/day);
DERM – dermal uptake factor (unitless);
VF – volatilization factor (m^3/kg); and
RF – retention factor (unitless).

2.2 Model Parameterization

The exposure parameters, models, concentration data, risk factors, and assumptions used in the current assessment were obtained from a number of sources, including U.S. Environmental Protection Agency (USEPA) guidance documents, published literature, the internet, and Clariant Corporation's (Clariant's) database. Input parameters are summarized in Table 1. The paragraphs below discuss each input parameter in detail.

2.2.1 Body Weight

The receptor of interest in the carpet scenario was a young child who is expected to be in direct contact with carpeted surfaces as a result of normal daily activities, such as playing, walking, and crawling. The range of age within this group can conceivably span from 1 to 10 years. The calculated average body weight for children of that age was 21.8 kg (USEPA, 2000) (Table 1).

2.2.2 Temporal Parameters

The time scale of the exposure and risk estimate was set to coincide with the useful life span of a residential carpet. According to an industry source, carpet warranties may span from 5 to 20 years. However, a typical carpet lasts about 10 years (Bigger and Bigger, 2004). Therefore, the exposure duration in this assessment was assumed to be 10 years. This is equivalent to the 3,650 days used as the averaging time in non-cancer hazard calculations. For the cancer risk assessment, a default life expectancy of 70 years was used to derive the lifetime average daily dose (25,550 days) (USEPA, 1997, 2002) (Table 1). The exposure frequency was set to the default of 350 days per year (USEPA, 1997, 2002) and the event frequency at one event per day.

2.2.3 Ingestion Parameters

The primary mode of tPCB intake in this exposure scenario was assumed to be via the incidental ingestion of carpet fibers/dust as a result of the mouthing of carpet surfaces, toys, hands, and feet. Because no ingestion rate data for the carpet fiber were readily available in the published literature, a conservative assumption was made that the carpet fiber intake by children is comparable to that of soil dust. According to Moya et al. (2004), children consume an average of 193 mg of soil and dust per day. However, the authors also stated that the daily consumption of soil alone is 138 mg/day. Therefore, an average dust ingestion rate of 55 mg/day can be estimated by subtracting 138 mg/day from 193 mg/day. That value was used to approximate the daily fiber ingestion rate (Table 1). A bioavailability factor was introduced into this component of the exposure/risk model to account for the proportion of the tPCBs in carpet that may be dislodged via digestive tract activities. This factor was set to range from 1% to 100% (Table 1) due to uncertainty as to its real empirical magnitude.

2.2.4 Inhalation Parameters

The inhalation rate of the receptor was set at 10.4 m^3/day, which is the average estimate for children ranging in age from 1 to 10 years old (USEPA, 2000) (Table 1). The tPCB vapor contribution to the overall exposure burden was estimated via a set of empirical models derived from air chamber experiments (Equations 2 to 4; Bennet and Furtaw, 2004). The required parameters in these models include carpet thickness, carpet area mass (also called face weight), and vapor pressure. Average carpet thickness was set to 0.0129 m, and average face weight was set to 1,700,000 mg/m^2 based on information obtained from the carpet industry (Radiant Panel Association, 2004; Carpet USA, 2004) (Table 1). The vapor pressure parameter was set to 0.0069 Pa and consisted of a mean of all values for PCB congeners 44 and 70 reported in the compendium by MacKay et al. (1992) (Table 1). To account for dilution due to ventilation, an AE was added to Equation 6. The value of that factor was based on the average number of air exchanges in a residential dwelling over 1 week.

2.2.5 Dermal Uptake Parameters

According to the USEPA (2000), the skin surface area available for contact during warm-weather play of children, with 32% of the total skin surface area exposed, is 2,763 cm^2/day (Table 1). The adherence factor, or the amount of material remaining on the skin after contact, was estimated at 0.00724 mg/cm^2 (USEPA, 2000). This value reflects soil adherence for children: post-activity; indoors; and on hands, arms, legs, and feet. An assumption was made that carpet fibers behave similarly to soil particles. The USEPA's default value for the dermal absorption factor for tPCBs in soil of 14% (USEPA, 2001) was adopted as the default value in this screening-level risk assessment.

2.3 Hazard and Risk Reference Values

The non-cancer reference dose for PCBs was 0.00002 mg/kg/day (reference dose for Aroclor 1254; USEPA, 2002). The cancer slope factor was 0.07 $(mg/kg/day)^{-1}$, and it represented the lowest risk and persistence category recommended by the USEPA (2002). The target risk used in the calculation was the low end of the USEPA's "acceptable risk range" of 1 in 1 million exposed individuals (1×10^{-6}) (USEPA, 1996, 1997, 2000) (Table 1). The target hazard quotient was set to 1.

2.4 Results and Discussion

New carpet data consist of a revised calculation of the maximum concentration of tPCBs in carpet fiber based on results from Alta Labs (Table 2) and sales data information. Accordingly, the highest concentration of PCBs in pigment of a masterbatch product shipped to carpet fiber manufacturers was 470 ppm. With no more than 3% of that concentrate added to carpet, the maximum concentration of PCBs is 14.1 ppm.

The combined ingestion, inhalation, and dermal uptake may lead to allowable concentrations in carpet fiber, ranging from approximately 8 to 133 mg tPCBs/kg, depending on the magnitude of the bioavailability and retention factors (Table 3). In contrast, the acceptable concentrations of tPCBs in carpet fiber associated with a 1 in 1 million cancer risk are much higher and range from approximately 39 to 664 mg/kg (Table 3; Figure 2). Comparing the tPCB concentrations estimated in the finished product (carpet; 14.1 mg/kg) to the results from the current assessments suggests that, even at 100% bioavailability and 1% retention, it is highly unlikely that any cancer risk responses will be triggered. This conclusion is the same as that reached for the maximum carpet concentration of 16.4 ppm used in the April 11, 2005 report. Inspection of the results table for non-cancer hazard calculations reveals that the estimated maximum concentration in the final product (14.1 mg/kg) exceeds the acceptable concentrations under only three exposure conditions (when oral bioavailability is 100%). This

observation is somewhat different from the conclusion reached using the 16.4 ppm maximum in the April 11, 2005 report, where six exposure conditions (for oral bioavailability of 50% and 100%) were identified as potentially problematic. The risk management implications of this finding are tentative because of the uncertainty associated with the estimate of the maximum carpet concentration, retention factor, and oral bioavailability. However, given the extensive level of conservatism and the low likelihood of PCBs being 100% bioavailable, it is doubtful that children exposed to carpet would experience any adverse health effects.

3. Food Wrap Scenario

The food wrap scenario was based on the potential exposure of general population to a dual-layer wrap product in which the tinted outer non-food contact layer of the wrap contains the affected pigment. The analysis of this scenario was based on the methodology published in the Federal Register Notice (62 Fed. Reg. 9365, March 3, 1997). In the risk analysis of April 11, 2005, a category-specific concentration of 1.1 mg tPCBs/kg was used under the conservative assumption that all products contained in the packing film, tape, and food tray category could have such a high concentration. Note that the actual concentration in packing film was reported at 0.06 ppm; this concentration was later revised to 0.34 ppm. The PCB concentration in tape (representative product with the highest concentration) was revised from 1.1 mg tPCBs/kg to 2.4 mg tPCBs/kg. The updated calculations are as follows. Assuming that each square inch of film contacts 10 grams of food (the Food and Drug Administration's [FDA's] standard assumption) and that the film face weight is 0.035 g/in^2 (Clariant, undated), the maximum concentration of tPCBs in the contacted food was estimated at 0.0084 mg/kg food[1]. To estimate the tPCB exposure of a person eating food (cheese), the calculated tPCB concentration must be multiplied by the amount of cheese consumed by a typical consumer. According to Smiciklas-Wright et al. (2002), average consumption of cheese is 0.026 kg per person per day. Given the average body weight of an adult of 70 kg, the exposure rate to tPCBs is 0.0000031[2] mg tPCBs/kg BW/day.

3.1 Results and Discussion

Comparing the calculated exposure (based on packing tape) to the non-cancer hazard threshold of 0.00002 tPCBs mg/kg BW/day (Table 1) reveals that the worst-case cheese exposure is about 6-fold lower than the trigger associated with non-cancer effects. The exposure associated with food wrap having a PCB concentration of 0.34 ppm would be about 45 times below the non-cancer threshold[3]. To estimate cancer risk, the estimated daily exposure must be averaged over a lifetime. According to Smiciklas-Wright et al. (2002), the maximum consumption rate of natural cheese for all age groups and genders is 16.2%. Assuming that there are three meals per day, the number of eating occasions in one year equals to 1,095. Thus, the number of eating occasions where cheese is consumed equals 177.4. Assuming three meals per day, the annual rate of cheese consumption

[1] 2.4 mg tPCBs/kg film x 0.000035 kg film /in^2 film x 1 in^2 /0.01 kg food (cheese) = 0.0084 mg tPCB/kg food (cheese)
[2] 0.0084 mg tPCBs/ kg cheese x 0.026 kg cheese/person/day x person/70 kg = 0.0000031 mg tPCBs/ kg BW/day

[3] 0.34 mg tPCBs/kg film x 0.000035 kg film /in^2 film x 1 in^2 /0.01 kg food (cheese) = 0.00119 mg tPCB/kg food (cheese)
0.00119 mg tPCBs/ kg cheese x 0.026 kg cheese/person/day x person/70 kg = 0.0000004 mg tPCBs/ kg BW/day

is equivalent to approximately 59 days. This number was used as the exposure frequency. Exposure duration was set to 70 years, and the averaging time was set to 25,550 days. Multiplying the daily exposure rate of 0.0000031 mg tPCB/kg BW/day (based on packing tape) by 59 days/year and 70 years and dividing the product by 25,550 days yields a lifetime-averaged exposure rate of 0.0000005 mg tPCB BW/day. In terms of the cancer risks (0.000014 mg tPCB/kg BW/day; Table 1), the estimated exposure resulting from cheese consumption is about 28 times lower than that needed to exceed the cancer level risk of 1 in 1 million. Considering the food warp alone (0.34 ppm), the calculated exposure would be 217 times lower than that associated with the acceptable level of cancer risk. This analysis shows that the potential exposure to tPCBs resulting from eating food (cheese) wrapped in red film is very low and highly unlikely to result in any toxicological responses in the population at large.

4. Conclusions

Despite high-end exposure assumptions, the concentrations determined to be within the USEPA's acceptable cancer risk range were well above the maximum concentration of tPCBs estimated in final product (carpet or food wrap). Some of the conservative exposure scenarios for non-cancer hazards (i.e., 100% oral bioavailability) indicated that the allowable carpet concentrations may be lower than those estimated in the final product. However, given the redundant conservatism built into the assessment, it is likely the risks and hazards are overstated. Therefore, the current analysis using updated information on the maximum concentration in carpet and food wrap suggests that there is no unacceptable risk and that there are no obvious public health concerns associated with the pigments in consumer products.

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6. Tables

Table 1. Exposure and Risk Model Input Parameters

Parameter	Value	Source
General		
Exposed Population: Young Children (yrs)	1 to 10	USEPA (2000)
Body Weight (1 to 12 yrs old; kg)	21.8	USEPA (2000)
Carpet Life Span (yrs)	10	Bigger and Bigger (2004)
Exposure Duration (yrs)	10	equal to carpet life
Exposure Frequency (days/year)	350	USEPA (1997; 2002)
Life Expectancy (yrs)	70	USEPA (1997; 2002)
Averaging Time: non-cancer (days)	3,650	USEPA (1997; 2002)
Averaging Time: cancer (days)	25,550	USEPA (1997; 2002)
Ingestion		
Dust (soil) Ingestion Rate (children; mg dust/day)	55	Moya et al. (2004)
Bioavailability of PCBs in Fiber (ingestion and inhalation; %)	1, 5, 10, 50, and 100	assumption
Inhalation		
Inhalation Rate (1 to 10 yrs old; m^3/day)	10.4	USEPA (2000)
Complete Air Exchange Rate (1/week; based on 18 exchanges/day)	126	Murray and Burnmaster (1995)
Vapor Pressure of PCB 44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Carpet Thickness (m)	0.01286	RPA (2004)
Carpet Area Mass (face weight; mg/m^2)	1,700,000	Carpet USA (2004)
Retention Factor (unitless)	0.001 to 0.01	Assumption
Dermal		
Dust Adherence Factor for children post-activity indoors on hands, arms, legs, feet (mg/cm^2)	0.00724	USEPA (2000)
Contact Skin Surface Area during warm-weather play with 32% skin exposed (cm^2/day)	2,763	USEPA (2000)
Dermal Uptake Factor	0.14	USEPA (2001)
Hazard and Risk Reference Values		
Target Hazard Quotient	1	USEPA (1997; 2002)
Non-Cancer Reference Dose (mg/kg BW/day)	0.00002	USEPA (2002)
Cancer Slope (mg/kg BW/day)$^{-1}$	0.07	USEPA (2002)
Target Cancer Risk	1×10^{-6}	USEPA (1997; 2002)
Target Lifetime Average Daily Dose (mg/kg BW/day)	0.000014	equal to acceptable risk over cancer slope

Table 2. Results of Alta Labs Analysis of PCB Congener Composition in Pigment Red 114/ 214

Lot Sample	US62253701	USEA000373	US62254106	US63385702	US63385703	US63385704	US63385705	USEA000164	USEA000165
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%	%
mono (1-3)	0.0016	0.0055	0.00089	0	0	0	0.00067	0.00090	0
di (4-15)	0.010	0.013	0.011	0.0058	0.0048	0.0044	0.0064	0.0050	0.0053
tri (16-39)	0.53	0.65	0.55	0.34	0.31	0.36	0.37	0.36	0.37
tetra (40-81)	99.091	98.94	99.059	99.41	99.49	99.38	99.44	99.52	99.44
penta (82-127)	0.34	0.37	0.36	0.23	0.18	0.25	0.18	0.093	0.17
hexa (128-169)	0.023	0.024	0.018	0.0093	0.0090	0.013	0.0072	0.012	0.0093
hepta (170-193)	0.00020	0	0	0	0	0	0	0.00016	0
octa (194-205)	0	0.000079	0	0	0	0	0	0.000091	0
nona (206-208)	0.00013	0	0	0	0	0	0	0.000011	0
deca (209)	0	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.63	99.61	99.62	99.76	99.81	99.74	99.82	99.89	99.82
Total Penta-Deca	0.37	0.39	0.38	0.24	0.19	0.26	0.18	0.11	0.18

Table 2, continued

Lot Sample	USEA000303	US62253702	US62253721	US62313816	MXSC313501	MXSC313502	US63268101	US63268102	US63268103
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%	%
mono (1-3)	0	0	0	0	0	0	0	0	0.0043
di (4-15)	0.0044	0	0.0025	0.0017	0.0021	0.0019	0.019	0.0050	0.0079
tri (16-39)	0.26	0.38	0.37	0.39	0.37	0.38	0.30	0.24	0.25
tetra (40-81)	99.52	99.39	99.38	99.38	99.48	99.47	99.46	99.53	99.52
penta (82-127)	0.20	0.22	0.24	0.21	0.14	0.15	0.21	0.22	0.21
hexa (128-169)	0.0091	0.014	0.011	0.016	0.0090	0.0090	0.014	0.0082	0.0091
hepta (170-193)	0	0	0	0	0	0	0	0	0
octa (194-205)	0	0	0	0	0	0	0	0	0
nona (206-208)	0	0	0	0	0	0	0	0	0
deca (209)	0	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.79	99.77	99.75	99.77	99.85	99.85	99.77	99.77	99.79
Total Penta-Deca	0.21	0.23	0.25	0.23	0.15	0.15	0.23	0.23	0.21

Table 2, continued

Lot Sample	US62253719	US62253711	US63268104	US63385701	US63385706	USEA000302	USEA000166	USEA000166(dup)
PCB Homolog (Congener Range)	%	%	%	%	%	%	%	%
mono (1-3)	0.00079	0.0028	0.032	0.00088	0.00084	0.00051	0.00070	0.00056
di (4-15)	0.0089	0.010	0.035	0.018	0.0066	0.0076	0.0085	0.0079
tri (16-39)	0.39	0.36	0.37	0.39	0.33	0.36	0.43	0.47
tetra (40-81)	99.29	99.29	99.16	99.24	99.43	99.32	99.31	99.25
penta (82-127)	0.30	0.33	0.39	0.33	0.22	0.29	0.24	0.25
hexa (128-169)	0.015	0.010	0.017	0.015	0.015	0.015	0.017	0.017
hepta (170-193)	0	0	0	0	0	0	0	0
octa (194-205)	0	0	0	0	0	0	0	0
nona (206-208)	0	0	0	0	0	0	0	0
deca (209)	0	0	0	0	0	0	0	0
Total	100	100	100	100	100	100	100	100
Total Mono-Tetra	99.69	99.66	99.60	99.65	99.77	99.69	99.74	99.73
Total Penta-Deca	0.31	0.34	0.40	0.35	0.23	0.31	0.26	0.27

Table 3. August 2005 Revised Risk-Based Concentrations (mg/kg) of tPCBs in Carpet Fiber

Oral Bioavailability Factor	Acceptable Concentration in Carpet Fiber (mg tPCB/kg)		
	Retention Factor		
	0.001	0.005	0.01
Non-Cancer Hazard			
0.01	133	122	111
0.05	81	77	72
0.10	54	52	50
0.50	15	15	15
1.00	7.9	7.8	7.8
Cancer Risk			
0.01	664	610	554
0.05	404	384	361
0.10	271	262	251
0.50	75	74	73
1.00	39	39	39

VersarINC

MEMORANDUM

TO: Laura Casey

cc: 11.1126.2000.001
Jim Buchert

FROM: Diane Sinkowski

DATE: December 16, 2005

SUBJECT: Review of Clariant/BBL "Addenda to Conceptual Exposure Model Report (August 2004 Revision) and Exposure and Screening-Level Risk Assessment Report (April 11, 2005 Revision), Red Pigment Project" (September 16, 2005)

Per your technical directive (November 15, 2005), Versar has reviewed Clariant's September 16, 2005, submittal (herein identified as the *August 2004 Addendum* and the *April 2005 Addendum*). Below are Versar's comments, based on the items specified in the technical direction.

- Are the formulas provided in the *Addenda* appropriate and are the proposed exposure/risk model input parameters appropriate based on the information provided? If not, please provide comments and/or recommendations using appropriate EPA procedures and guidance.

  The formulas provided in the *April 2005 Addendum* are appropriate for estimating the risk-based concentration of PCBs in carpeting and the potential risk associated with exposure to PCBs in food wrap. Two issues remain with the selected input parameters. As discussed in Versar's August 1, 2005, memorandum, the worst-case risk-based concentration for PCBs in carpet fiber would be calculated by using a retention factor (RF) of 1.0, where all the PCBs in the carpeting are volatilized. Clariant did provide calculations of PCB carpet concentration based on the RF of 1.0 in the spreadsheet "forward_calcs2_7.5_1.xls". However, Table 3, page 6-1, of the *April 2005 Addendum*, does not present these carpet concentrations associated with the worst-case RF assumption. Also, the use of the weekly air exchange rate (AE) of 126, shown in Table 1, page 6-1, of the *April 2005 Addendum*, was discussed in Versar's August 1, 2005, memorandum. This AE was noted by Clariant as being based on an hourly AE rate of 0.35/hr, but is actually based on a higher AE rate of 0.75/hr. The weekly AE rate based on 0.35/hr would be 58.8. As noted in the August memorandum, Clariant had agreed to use a lower AE of 0.35/hr or, at the very least, the typical or average value of 0.45 AEs per hour, as given in the *Exposure Factors Handbook*, corresponding to a weekly AE of 75.6. According to Table 1 of the *April 2005 Addendum*, the AE rate of 126 is still being used in the calculations.

- Referring back to the August 1, 2005 Memorandum from Versar to Laura Casey (EPA-HQ), would the information provided in the Addenda affect any of these comments and/or calculations?

  The *April 2005 Addendum* calculates the risk-based concentrations of total PCBs in carpet fiber, and does not use the measured PCB concentration. Since the measured concentration is not used in the calculations, the calculations would not be affected by the new maximum value of 14.1 ppm (from the *August 2004 Addendum*). The revised PCB concentrations in food wrap, 2.4 and 0.34 ppm, were used to update the exposure estimate associated with the product. The results did not significantly change from the original estimate, based on 1.1 ppm.

- Given all information provided, does Versar have any comments and/or conclusions with respect to the appropriate input parameters which should be considered in EPA's final evaluation of the risk to end-users from the evaluated products (e.g. the carpet and food wrap)?

  As stated in first comment, the worst-case RF of 1.0 has not been included in the calculations of the risk-based concentrations (mg/kg) of total PCBs in carpet fiber (Table 3, page 6-1, of the revised April 11, 2005, exposure and screening-level assessment). Also, the more conservative AE of 0.35/hr has also not been used in the calculations included in the *April 2005 Addendum*. Versar recommends that these values be included in the *Addenda* in order to represent the most conservative exposure conditions.

- Based on Versar's review of the data usability assessment and Clariant conclusions, does Versar have any comments and/or conclusions with respect to data quality and/or its usability in the exposure model?

  Based on the data useability worksheet, it appears that the collected samples and resulting congener analyses should reflect the total PCB concentrations found in the carpet fiber manufactured with pigment reds 144/214.

- Based on the revised pigment concentrations and the revised estimated PCB concentration in the associated end products, does Versar have an opinion as to whether any other product should be evaluated or is the original assumption (e.g. carpet and food wrap are worst-case end uses with respect to exposure) still valid?

  Exposures to PCBs in carpet fiber and food wrap would be expected to still represent the worst-case exposure to end use products. The total PCB concentration of 14.1 mg/kg is the highest measured PCB concentration found in the identified industrial and consumer end use products. Additionally, assuming that residential children, a sensitive population, are exposed to the PCBs in carpeting via ingestion, inhalation, and dermal absorption should also correspond to the worst-case exposure. Also, the exposure estimate based on the assumption

that all the PCBs found in the food wrap are transferred to the cheese that has come into contact with the food wrap and that the cheese is ingested over a period of 70 years would represent a very conservative and worst-case scenario.

Please feel free to contact us if you have any questions.

Kimberly Tisa/R1/USEPA/US
12/19/2005 09:37 AM

To Mike.Teague@clariant.com
cc
bcc
Subject Re: RA Addendum - Comments

Mike-

I've received comments from Versar on the RA Addenda, revised September 1995. Please see attached.

Addenda Sept. 16, 2005 - Versar Comments 12162005.doc

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Subject Data Usability Response

Kim -

I've attached a composite document that attempts to answer your questions regarding data usability for the red pigment issue. The first three pages contain responses to EPA's RAGS Part D Appendix C Data Usability Worksheet. This worksheet focuses primarily on the usability of the analytical data from Alta Labs. We conclude that there is no reason to question the usability of the analytical data that represents the contaminant concentrations in the commercial lots of pigment.

The last page contains a table which details the basis for the three worst-case contaminant concentration calculations in carpet fiber that have been used in past risk assessments (3.8, 16.4 and 14.1 ppm). The rationale for all changes are documented in this table. Please note that as a result of this most recent data review, there is now a fourth number that could be used for the risk assessment (12.5 ppm). I'm sure that on the surface, the number of changes in this worst-case value brings into question its credibility and, therefore, its usability. However, please let me highlight three key points concerning the changes and the nature of this worst-case value.

1. The most significant change was the first, from 3.8 ppm to 16.4 ppm. This change primarily resulted from our decision to use the higher worst-case pigment concentration data from Alta Labs instead of

Clariant's in-house analytical data. This was the most conservative way to resolve the discrepancies between Clariant's data and the Alta Lab data, and represented a four-fold increase in the worst-case carpet fiber concentration estimate.

2. The other three changes primarily resulted from ever more detailed internal reviews of the Clariant Masterbatch (plastic pigment concentrate) manufacturing data and contaminant concentration calculation methods. The difference between these three concentration calculations is insignificant compared with the first change, and represents incremental refinement of internal data as a result of repeated review of the information available to me personally from our Masterbatch division. In other words, the tweaking of this value is an indication that the validity of the worst-case value has been questioned again and again and modified as appropriate. I do not foresee the need to modify this value again because all calculations and assumptions have been vetted top to bottom.

3. The overall effect of the last three worst-case carpet fiber concentration calculation changes on the conclusions of the risk assessment is minimal. There is little difference between the conclusions drawn from the risk assessment using the 16.4 value and those drawn from the assessment using the 14.1 value.

Further to point 3 above, please note that we have not submitted a formal risk assessment using the 12.5 value because it would not substantially affect the final conclusions of the prior assessments, nor resolve any of the uncertainties inherent in the risk assessments. The current data and risk assessment methodology have been used to the fullest extent possible, and we believe that there is little to be gained by continued tweaking.

It would be very helpful at this point for Clariant to know whether EPA and Versar accept that the sum total of conservative assumptions outweigh the uncertainties in the risk assessment. If you do not agree that this is the case, please tell us specifically what we need to do to make the risk assessments acceptable to you. As always, we are available for a meeting or conference call to discuss details. I look forward to your response.

Best regards,

Mike

Mike Teague
Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205 USA
Office Phone: 704.331.7104
Cell Phone: 704.904.8707
FAX: 704.330.1528

Data Usability Worksheet.pdf

MEMORANDUM

To: Mr. Jim Buchert, Versar, Inc.

From: Laura Casey, OPPT/NPCD/FOB

RE: Technical Direction to Work Assignment 0-1

Subject: Clariant Corporation, Coventry, Rhode Island

EPA-Region 1 has received from the Clariant Corporation, an *Addenda to the Conceptual Exposure Model Report* (August 2004 Revision), and *Exposure and Screening Level Risk Assessment Report* (April 11, 2005 Revision), dated September 16, 2005 associated with its Clariant Red Pigment Project. As previously indicated, these Red Pigments have been used in a wide variety of consumer products. (Versar has previously reviewed and provided comments on these past reports.) The most recent comments, dated August 1, 2005, were provided on exposure route concentrations. Using worst-case scenarios and data previously provided on the end-product estimated concentrations, it appeared that the end products evaluated (namely the carpet and food wrap) would be found not to present an unreasonable risk.

In this September 16, 2005 *Addenda*, Clariant has provided an Addendum to the August 2004 Report and the April 11, 2005 Report, which incorporates new data regarding pigment contaminant concentration. The effect is that the original estimated end-product concentrations have increased for many products. Region 1 will provide this *Addenda* to Versar in hard copy via certified mail.

EPA has also received a response to its request regarding data usability. Clariant has conducted a data usability assessment of all data in accordance with RAGS Part D, Appendix C and has provided this assessment to EPA via e-mail. Region 1 will provide this data usability assessment to Versar in hard copy via certified mail.

Please review these documents for the following:

- Are the formulas provided in the *Addenda* appropriate and are the proposed exposure/risk model input parameters appropriate based on the information provided? If not, please provide comments and/or recommendations using appropriate EPA procedures and guidance.

- Referring back to the August 1, 2005 Memorandum from Versar to Laura Casey (EPA-HQ), would the information provided in the Addenda affect any of these comments and/or calculations?

- Given all information provided, does Versar have any comments and/or conclusions with respect to the appropriate input parameters which should be considered in EPA's final evaluation of the risk to end-users from the evaluated products (e.g. the carpet and food wrap)?

- Based on Versar's review of the data usability assessment and Clariant conclusions, does Versar have any comments and/or conclusions with respect to data quality and/or its usability in the exposure model?

- Based on the revised pigment concentrations and the revised estimated PCB concentration in the associated end products, does Versar have an opinion as to whether any other product should be evaluated or is the original assumption (e.g. carpet and food wrap are worst-case end uses with respect to exposure) still valid?

Due Date: Please turn the review of these documents around by December 16, 2005. If there are any questions regarding this due date, please contact me at 202-566-1982.

Technical questions relating to this project may be addressed directly to Kim Tisa in Region 1 at 617-918-1527 or by e-mail at tisa.kimberly@epa.gov.

Mike.Teague@clariant.com
11/11/2005 11:42 AM

To Kimberly Tisa/R1/USEPA/US@EPA
cc js1@bbl-inc.com, APAWLISZ@bbl-inc.com, Erin.Russell@clariant.com, John.Paul@clariant.com
bcc
Subject Data Usability Response

Kim -

I've attached a composite document that attempts to answer your questions regarding data usability for the red pigment issue. The first three pages contain responses to EPA's RAGS Part D Appendix C Data Usability Worksheet. This worksheet focuses primarily on the usability of the analytical data from Alta Labs. We conclude that there is no reason to question the usability of the analytical data that represents the contaminant concentrations in the commercial lots of pigment.

The last page contains a table which details the basis for the three worst-case contaminant concentration calculations in carpet fiber that have been used in past risk assessments (3.8, 16.4 and 14.1 ppm). The rationale for all changes are documented in this table. Please note that as a result of this most recent data review, there is now a fourth number that could be used for the risk assessment (12.5 ppm). I'm sure that on the surface, the number of changes in this worst-case value brings into question its credibility and, therefore, its usability. However, please let me highlight three key points concerning the changes and the nature of this worst-case value.

1. The most significant change was the first, from 3.8 ppm to 16.4 ppm. This change primarily resulted from our decision to use the higher worst-case pigment concentration data from Alta Labs instead of Clariant's in-house analytical data. This was the most conservative way to resolve the discrepancies between Clariant's data and the Alta Lab data, and represented a four-fold increase in the worst-case carpet fiber concentration estimate.

2. The other three changes primarily resulted from ever more detailed internal reviews of the Clariant Masterbatch (plastic pigment concentrate) manufacturing data and contaminant concentration calculation methods. The difference between these three concentration calculations is insignificant compared with the first change, and represents incremental refinement of internal data as a result of repeated review of the information available to me personally from our Masterbatch division. In other words, the tweaking of this value is an indication that the validity of the worst-case value has been questioned again and again and modified as appropriate. I do not foresee the need to modify this value again because all calculations and assumptions have been vetted top to bottom.

3. The overall effect of the last three worst-case carpet fiber concentration calculation changes on the conclusions of the risk assessment is minimal. There is little difference between the conclusions drawn from the risk assessment using the 16.4 value and those drawn from the assessment using the 14.1 value.

Further to point 3 above, please note that we have not submitted a formal risk assessment using the 12.5 value because it would not substantially affect the final conclusions of the prior assessments, nor resolve any of the uncertainties inherent in the risk assessments. The current data and risk assessment methodology have been used to the fullest extent possible, and we believe that there is little to be gained by continued tweaking.

It would be very helpful at this point for Clariant to know whether EPA and Versar accept that the sum total

of conservative assumptions outweigh the uncertainties in the risk assessment. If you do not agree that this is the case, please tell us specifically what we need to do to make the risk assessments acceptable to you. As always, we are available for a meeting or conference call to discuss details. I look forward to your response.

Best regards,

Mike

Mike Teague
Clariant Corporation
4000 Monroe Road
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Cell Phone: 704.904.8707
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Data Usability Worksheet.pdf

DATA USEABILITY WORKSHEET
Site: CLARIANT CARPET EXPOSURE SCENARIO
Medium: CARPET FIBER

Activity	Comment
Field Sampling	
Discuss sampling problems and field conditions that affect data useability.	Only applicable to pigment sampling. No problems or adverse conditions were identified.
Are samples representative of receptor exposure for this medium (e.g. sample depth, grab vs composite, filtered vs unfiltered, low flow, etc.)?	The pigment samples were representative of the medium used in the coloring of carpet fibers. Samples analyzed were taken directly from retain samples of the finished pigment lots sold into commerce. Samples are inherently representative of entire blended lot because lot homogeneity is mandated by pigment color quality performance specifications for customers.
Assess the effect of field QC results on data useability.	Not applicable.
Summarize the effect of field sampling issues on the risk assessment, if applicable.	Note that direct exposure was to the end product (i.e. carpet) rather than the pigment directly. Therefore, measuring PCB levels in pigment rather than carpet is a conservative approach.
Analytical Techniques	
Were the analytical methods appropriate for quantitative risk assessment?	Alta Labs used the EPA-approved Method 1668.
Were detection limits adequate?	The detection limits were in the pg/g range and well below the levels detected in samples. Reporting limits are listed in the "RL" column on data sheets and correspond to the concentration of the low point of the initial calibration curve. The reporting limit can be considered the detection limit.
Summarize the effect of analytical technique issues on the risk assessment, if applicable.	There were no known issues with the analysis of the pigment samples by the third-party lab, Alta. Discrepancies were noted between Alta Lab data and Clariant in-house data. The risk assessment uses Alta Lab data exclusively because Alta Labs used a more precise analytical method, and because the highest PCB concentration values came from Alta. This is the most conservative approach.

Activity	Comment
Data Quality Objectives	
Precision - How were duplicates handled?	Duplicate results were not reported.
Accuracy - How were split samples handled?	Split samples were not collected.
Representativeness - Indicate any problems associated with data representativeness (e.g., trip blank or rinsate blank contamination, chain of custody problems, etc.).	The reporting limit was raised for several congeners due to chemical interference. However, none of these congeners were present in the samples. Some method blanks were reported as having detectable concentrations of PCBs. However, the amount detected was several orders of magnitude below that reported in the sample. Therefore, the overall effect on the results was very small.
Completeness - Indicate any problems associated with data completeness (e.g., incorrect sample analysis, incomplete sample records, problems with field procedures, etc.).	No problems associated with the pigment analysis were indicated.
Comparability - Indicate any problems associated with data comparability.	None.
Were the DQOs specified in the QAPP satisfied?	Due to the nature and size of the sample set, a formal Quality Assurance Project Plan was not created. However, the implied DQO for the PCB analyses was to obtain PCB concentration data free from interference, contamination, and detection limit issues. According to the results, this objective has been attained.
Summarize the effect of DQO issues on the risk assessment, if applicable.	There were no DQO issues reported.
Data Validation and Interpretation	
What are the data validation requirements?	Formal validation of the analytical data using standard approaches was not performed and was not deemed necessary. Carpet fiber PCB concentration calculations were checked and modified on several occasions. Due care was used to ensure that data are as accurate as possible.

Activity	Comment
What method or guidance was used to validate the data?	Not applicable.
Was the data validation method consistent with guidance? Discuss any discrepancies.	Not applicable.
Were all data qualifiers defined? Discuss those which were not.	All data qualifiers were provided.
Which qualifiers represent useable data?	Data with no qualifier, B (analyte also detected in method blank), and I (reporting limit raised due to chemical interference).
Which qualifiers represent unuseable data?	None reported.
How are tentatively identified compounds handled?	Not applicable.
Summarize the effect of data validation and interpretation issues on the risk assessment, if applicable.	Carpet fiber PCB concentration calculations were reviewed and checked on numerous occasions, which resulted in one significant and two slight modifications of the worst-case carpet fiber concentration. Please see the attached table which details the evolution of PCB concentration calculations for carpet fiber.

Explanation of Carpet Fiber PCB Concentration Estimate Changes

Value (ppm)	Risk Assessment Documents	Analytical Basis	Worst-Case End User Scenario	Basis of End Use Concentration	Reason for Change to Revised Value
3.8	**Conceptual Exposure Model and Preliminary Assessment for End Users of Pigment Red 144 and 214** August 31, 2004 **Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigments Red 144/214** December 6, 2004 **Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigments Red 144/214** February, 2005	Clariant internal laboratory analyses of finished pigment lots.	Clariant Masterbatch Single Pigment Concentrate (SPC) at 40% pigment loading sold to customer A.13 who could have used the SPC at a let-down ratio as high as 3%	Clariant Masterbatch marketing calculations of SPC PCB concentration at 126 ppm 126 ppm x 3% = 3.8 ppm.	Total PCB values from new analyses of pigment lots performed by external, third-party laboratory (Alta Laboratories) for purposes of obtaining congener-specific data called into question Clariant's internal laboratory data
16.4	**Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigments Red 144/214** April 11, 2005	Congener-specific analysis of each finished pigment lot performed by Alta Laboratories using EPA Method 1668. Highest concentration found in any single pigment lot was 1,370 ppm.	Clariant Masterbatch Single Pigment Concentrate (SPC) at 40% pigment loading sold to customer A.13 who could have used the SPC at a let-down ratio as high as 3%.	Instead of attempting to reconstruct Clariant Masterbatch marketing calculations, in the interest of time, assumed worst case scenario that customer A.13 received the most contaminated pigment lot in the worst case end user scenario. Therefore, 1,370 ppm x 40% pigment in SPC = 548 ppm in the Masterbatch SPC. Applying the let-down ratio of 3% to the SPC yields 548 ppm x 3% = 16.4 ppm in carpet fiber.	After submitting the April 11, 2005 report, additional effort was given to better understand the exact make-up of the most contaminated shipment of SPC to customer A.13. Customer A.13 did not receive and use an SPC shipment at 548 ppm PCB content because the most contaminated pigment lot (at 1,370 ppm) was not used to make the worst-case SPC.
14.1	**Addendum to Report: Conceptual Exposure Model and Preliminary Assessment for End Users of Pigments Red 144 and 214** September 16, 2005 **Addendum to Report: Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigments Red 144/214** September 16, 2005	Congener-specific analysis of each finished pigment lot performed by Alta Laboratories using EPA Method 1668. Highest concentration found in any single pigment lot was 1,370 ppm	Clariant Masterbatch Single Pigment Concentrate (SPC) at 40% pigment loading sold to customer A.13 who could have used the SPC at a let-down ratio as high as 3%.	Masterbatch SPC lot XO1269 (11,291 lbs) was the highest PCB concentration SPC that was received and used by customer A.13. It was created using differing amounts of two separate lots of contaminated red pigment. Other, non-contaminated pigments were also used to create this SPC for a total estimated pigment weigh of 4,004 lbs. The contaminated pigment lots, their contaminant level and quantity used were: USEA000164 1,265.8 ppm PCB 1,364 lbs used in SPC USEA000165 1,127.4 ppm PCB 2,640 lbs used in SPC The equation used to calculate the final SPC lot PCB concentration was as follows. (((1,364 lbs/4,004 lbs) x 1,265.8 ppm) + ((2,640 lbs/4,004 lbs) x 1,127.4 ppm)) * 40% = 470 ppm. Applying the let-down ratio of 3% to the SPC yields 470 ppm x 3% = 14.1 ppm in carpet fiber	Further review of the batch record for SPC lot XO1269 and the method used to calculate the final SPC lot PCB concentration revealed two small mistakes. The actual pigment quantities used were inadvertenly inflated to a theoretical maximum of 40%. The actual pigment loading in this lot was 37%. Furthermore, a small amount of a third contaminated pigment lot was not accounted for in the mixture
12.5	**Modified assessment not yet submitted to Agency** November, 2005	Congener-specific analysis of each finished pigment lot performed by Alta Laboratories using EPA Method 1668. Highest concentration found in any single pigment lot was 1,370 ppm.	Clariant Masterbatch Single Pigment Concentrate (SPC) at 37% pigment loading from various pigment lots was sold to customer A.13 who could have used the SPC at a let-down ratio as high as 3%	Masterbatch SPC lot XO1269 (11,291 lbs) was the highest PCB concentration SPC that was received and used by customer A.13. It was created using differing amounts of five separate lots of red pigment. Two of these pigment lots had no PCB contamination, and together they formed 176 lbs of pigment used in the SPC. The other three pigment lots, their contaminant level and quantity used were: USEA000164 1,265.8 ppm PCB 1,364 lbs used in SPC USEA000165 1,127.4 ppm PCB 2,640 lbs used in SPC US63385702 826.2 ppm PCB 12 lbs used in SPC. The final PCB concentration of the SPC is found by multiplying the quantity of each pigment lot by its respective PCB concentration, summing these values and then dividing by the total mass of the SPC lot. ((1,364 lbs x 1,265.8 ppm) + (2,640 lbs x 1,127.4 ppm) + (12 lbs x 826.2 ppm))/11,291 lbs = 417 ppm. Applying the let-down ration of 3% in carpet fiber yields 417 ppm x 3% = 12.5 ppm	No need to revise this calculation.

Mike.Teague@clariant.com
10/20/2005 08:28 AM

To Kimberly Tisa/R1/USEPA/US@EPA
cc Erin.Russell@clariant.com, js1@bbl-inc.com, John.Paul@clariant.com
bcc
Subject Re: Revised Assessment Table and Versar Comments

Kim -

I just want to drop you a note and let you know I'm not ignoring your messages. I know you and John Schell have had several discussions over the past few days, and John and I were just able to catch up with each other this morning. We're currently working on a data usability document that we hope to be able to send you sometime next week. I'll let you know as soon as it's ready.

Regards,

Mike

Mike Teague
Clariant Corporation
4000 Monroe Road
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Office Phone: 704.331.7104
Cell Phone: 704.904.8707
FAX: 704.330.1528

tisa.kimberly@epamail.epa.gov

10/12/2005 04:21 PM

To Mike.Teague@clariant.com
cc Erin.Russell@clariant.com, js1@bbl-inc.com
Subject Re: Revised Assessment Table and Versar Comments

Mike-

I left you a voice message regarding data quality and have also discussed this with John. Given that we're trying to make a determination on the carpet, I need to insure that the data is of sound quality and that we're using the appropriate inputs.

In addition, I had received comments from Versar in August regarding the

revised calculations provided by you on June 20, 2005. I was waiting for the updated PCB concentrations before providing the comments to you. I have reviewed the Addenda (which incorporates the revised PCB data). Based on this review, I am providing Versar's comments to you and ask that you check the calculations in the Addenda to insure they are accurate and correct. If not, please let me know and I will hold the Addenda and wait for revision before sending to Versar.

Please call me if you have any questions.

(See attached file: Review of Clariant Calculations 08012005.wpd)

Kimberly N. Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

phone: 617.918.1527
fax: 617.918.0527
e-mail: tisa.kimberly@epa.gov
[attachment "Review of Clariant Calculations 08012005.wpd" deleted by Mike Teague/CLARIANT]

JOHN SCHELL
<js1@bbl-inc.com>
10/13/2005 01:08 PM

To Kimberly Tisa/R1/USEPA/US@EPA
cc Mike Teague <Mike.Teague@clariant.com>
bcc
Subject Re: Revised Assessment Table and Versar Comments

Kim:

Mike and I have exchanged voice messages - he's on the road today but we'll talk tomorrow(I hope). I think I have the source of the 3 different numbers clarified and will present that to you after I run it by Mike

You mentioned on the phone that because of the confusion in these values you will need a data usability and data quality assessment. Do you want us to follow the data usability worksheet from Appendix C of RAGS Part D or something more narrative in nature? For the data quality portion, we have the QA/QC package from the lab. Is that what you are looking for?

Also, we'll make the change on the AF, and as pointed out by Versar it won't have a substantial impact on the results of the analysis.

Versar also provided the following comment "For the mass-balance approach, it was assumed that all tPCB mass in the carpet was released, at a constant rate, over its 10-year lifetime (details on the calculation can be provided on request)."
Since this is virtually impossible based on the production process, how would you like us to handle this comment? We could address it in the uncertainty section and include Versar's calculation Just let me know your preference and I'll have the report modified.

John

Spoke w/ John on 10/13/05 re: issues.
(1) need both internal lab QC discussion & data usability discussion for all labs w/ data inputs used in assessment.
(2) re: 8/01/05 - don't need to respond to Versar's calcs only to improper AF used - MMTisa

John D. Schell, Ph.D.
Vice President/Toxicologist
BBL Sciences
2929 Briarpark Dr., Suite 329
Houston, TX 77042
P: 713.785.1680 (X14)
F: 713.785-1640

>>> <tisa.kimberly@epamail.epa.gov> 10/12/05 3:21 PM >>>
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(See attached file: Review of Clariant Calculations 08012005.wpd)

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U.S. Environmental Protection Agency
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Boston, MA 02114-2023

phone: 617.918.1527
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Kimberly Tisa/R1/USEPA/US
10/12/2005 04:07 PM

To Mike.Teague@clariant.com
cc Erin.Russell@clariant.com, js1@bbl-inc.com
bcc
Subject Re: DRAFT Revised Assessment Table

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I left you a voice message regarding data quality and have also discussed this with John. Given that we're trying to make a determination on the carpet, I need to insure that the data is of sound quality and that we're using the appropriate inputs.

In addition, I had received comments from Versar in August regarding the revised calculations provided by you on June 20, 2005. I was waiting for the updated PCB concentrations before providing the comments to you. Given the data, I am providing Versar's comments to you and ask that you check the calculations in the Addenda to insure they are accurate and correct. If not, please let me know and I will hold the Addenda and wait for revision before sending to Versar.

Please call me if you have any questions.

Review of Clariant Calculations 08012005.wpd

Kimberly N. Tisa, PCB Coordinator (CPT)
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Mike.Teague@clariant.com
07/08/2005 05:24 PM

To Kimberly Tisa/R1/USEPA/US@EPA
cc John.Paul@clariant.com, Erin.Russell@clariant.com, js1@bbl-inc.com
bcc
Subject DRAFT Revised Assessment Table

Kim -

Attached you'll find a draft revised Table 2 (non-CBI version) from the August 2004 Screening Assessment report. Please consider this draft because I was not able to get the revisions to BBL for their review prior to today. John Schell will be back in his office on Monday and will hopefully have time to take a look at it and make any changes he sees are necessary. Once he's signed off on it, I can either email you a final version and we can leave it at that, or we can submit CBI and non-CBI hardcopies to replace the pages from the August 2004 report. Alternatively, we can submit a complete report document containing the revisions. Please advise how you want to handle it.

A couple of items to note. Any changes made to the contaminant concentrations show up in red font on the spreadsheet. In my opinion, I don't think the new concentrations affect the conclusions drawn from the original assessment; however, I'll let our expert rule on that early next week.

Secondly, I regret to inform you that as I delved into the detailed data for Tier II customers, I discovered one that was inadvertently omitted from the original information we submitted to you. This customer is a customer of our Masterbatch division and so took pigment diluted in plastic as a delivered product. They used it to make monofilament strands that comprise industrial conveyor belt matting. At this point, indications are that the belts are used in paper mills to move pulp, but we'll need some time next week to gather more information. I've added a new category "S" to the revised table which captures what we know to date.

John Schell emailed me and said BBL almost has their calculations complete for Versar, so we should be able to get that to you next week as well.

Regards,

Mike

Mike Teague
Vice President, ESHA
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----- Forwarded by Mike Teague/CLARIANT on 07/08/2005 04:53 PM -----
Mike Teague/CLARIANT

06/17/2005 04:27 PM

To <tisa.kimberly@epamail.epa.gov>
cc John Paul/CLARIANT@CLARIANT, Erin Russell/CLARIANT@CLARIANT, js1@bbl-inc.com

Classification: Internal

Subject Revised Assessment Table

Kim -

You asked yesterday during our call for an estimated submittal date for the recalculation of contaminant in all end uses (basically an update of Table 2 from the August 31, 2004 report using Alta Lab data).

As you know, two separate business divisions supplied pigments to customers, some of which then further processed the material before selling it to the end user. Since the sales data is 1.5 years old, our business people need to go back into our documentation to refamiliarize themselves with the connections between lots sold to customers and contaminant concentrations. The sales trail from the Pigments division is pretty straightforward, and John Paul is having those people look at the lot-level sales information while he's gone next week. The sales trail from the Masterbatches division, although documented, is more complicated and less understandable to a nonbusiness person (in other words, I can't do it without a lot of help). I've made contact with the expert in Masterbatches who did this work for us initially, and he has agreed to work on the Masterbatch product calculations while I'm out next week. I'm assuming these people can get results back to me within one week, but that's a guess.

Once I get the new data, I still have to match them up with the customer let-down data, recalculate the end product concentrations and then pass all that information on to BBL for final sign-off as to the need or not for further assessment. Since I'm travelling on business the first part of the week of the 27th, I won't be able to begin this task in earnest until June 30. Therefore, I'm going to say I can have the revised table to you no later than July 8 (we've got the 4th holiday in that week too). I know that probably seems like a long time just to rework a table, but please understand this isn't a trivial exercise and that we're trying to provide you with the most reliable data we can given the circumstances of our schedules. I'll certainly send it earlier if at all possible.

As agreed, we need to keep the carpet assessment moving along with BBL in my absence. John Schell sent his contact information to you separately, so please copy him on Versar's instructions next week.

Thanks.

Mike

Mike Teague
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Office Phone: 704.331.7104
Cell Phone: 704.904.8707

FAX: 704.330.1528

DRAFT Table_2_Revised.pdf

DRAFT REVISED Table 2

Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with HHRA?
			A (10 ppm)	B (1 ppm)	
A. Fiber and Carpet Yarn					
A.1	3.1	Y	NA	Y	Y
A.2	1.6	Y	NA	Y	Y
A.3	NR	?	?	?	?
A.4	NR	?	?	?	?
A.5	3.1	Y	NA	Y	Y
A.6	2.4	Y	NA	Y	Y
A.7	2.6	Y	NA	Y	Y
A.8	3.1	Y	NA	Y	Y
A.9	5.5	Y	NA	Y	Y
A.10	4.1	Y	NA	Y	Y
A.11	NR	Y	NA	?	?
A.12	4.1	Y	NA	Y	Y
A.13	14.1	Y	NA	Y	Y
A.14	4.1	Y	NA	Y	Y
A.15	3.4	Y	NA	Y	Y
A.16	NR	?	?	?	?
B. Intravenous Bag Labels					
B.1	<10	Y	N	NA	N
B.2	<10	Y	N	NA	N
B.3	<10	Y	N	NA	N
B.4	<10	Y	N	NA	N
B.5	<10	Y	N	NA	N
B.6	<10	Y	N	NA	N
C. Air, Fuel, Oil, and Refrigerant Tubing					
C.1	1.0	Y	N	NA	N
C.2	0.3	Y	N	NA	N
C.3	3.9	Y	N	NA	N
D. Snow Flaps					
D.1	8.2	Y	N	NA	N
D.2	0.1	Y	N	NA	N
E. Automotive Electrical Connectors and Spacers					
E.1	1.5	Y	N	NA	N
E.2	1.5	Y	N	NA	N
F. Tools					
F.1	0.520	Y	N	NA	N
F.2	1.5	Y	N	NA	N
F.3	2.5	Y	N	NA	N
G. Accessories					
G.1	7.6E-04	Y	N	NA	N
G.2	0.5	Y	N	NA	N
G.3	1.0	Y	N	NA	N
G.4	1.2	Y	N	NA	N
H. Injection Molded Doghouses					

DRAFT REVISED Table 2
Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with HHRA?
			A (10 ppm)	B (1 ppm)	
H.1	0.15	Y	N	NA	N
I. Packing Film, Tape, and Food Trays					
I.1	2.4	Y	NA	Y	Y
I.2	0.34	Y	NA	N	N
J. Textiles					
J.1	NR	Y	NA	?	?
J.2	NR	N[5]	NA	?	N
K. Gaskets					
K.1	0.52	Y	N	NA	N
L. Displays					
L.1	0.52	Y	N	NA	N
M. Syringe Containers					
M.1	0.08	Y	N	NA	N
N. Furniture and Flooring					
N.1	NR	Y	NA	?	?
N.2	NR	Y	NA	?	?
N.3	NR	Y	NA	?	?
O. Countertops					
O.1	0.1	Y	N	NA	N
O.2	0.1	Y	N	NA	N
O.3	0.1	Y	N	NA	N
O.4	0.1	Y	N	NA	N
O.5	0.1	Y	N	NA	N
O.6	0.1	Y	N	NA	N
O.7	0.1	Y	N	NA	N
O.8	0.1	Y	N	NA	N
O.9	0.1	Y	N	NA	N
O.10	0.1	Y	N	NA	N
P. Tubs and Spas					
P.1	0.1	Y	N	NA	N
P.2	0.1	Y	N	NA	N
P.3	0.3	Y	N	NA	N
P.4	0.1	Y	N	NA	N
P.5	0.1	Y	N	NA	N
P.6	0.1	Y	N	NA	N
P.7	0.1	Y	N	NA	N
P.8	0.1	Y	N	NA	N
P.9	0.1	Y	N	NA	N
P.10	0.1	Y	N	NA	N
P.11	0.1	Y	N	NA	N
P.12	0.1	Y	N	NA	N
P.13	0.1	Y	N	NA	N
P.14	0.1	Y	N	NA	N
P.15	0.1	Y	N	NA	N

DRAFT REVISED Table 2

Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with HHRA?
			A (10 ppm)	B (1 ppm)	
P.16	0.1	Y	N	NA	N
P.17	0.1	Y	N	NA	N
P.18	0.1	Y	N	NA	N
P.19	0.1	Y	N	NA	N
P.20	0.1	Y	N	NA	N
P.21	0.1	Y	N	NA	N
P.22	0.1	Y	N	NA	N
P.23	0.1	Y	N	NA	N
P.24	0.1	Y	N	NA	N
P.25	0.1	Y	N	NA	N
P.26	0.3	Y	N	NA	N
P.27	0.1	Y	N	NA	N
P.28	0.1	Y	N	NA	N
P.29	0.1	Y	N	NA	N
P.30	0.1	Y	N	NA	N
P.31	0.1	Y	N	NA	N
P.32	0.1	Y	N	NA	N
P.33	0.1	Y	N	NA	N
P.34	0.1	Y	N	NA	N
P.35	0.1	Y	N	NA	N
P.36	0.3	Y	N	NA	N
P.37	0.1	Y	N	NA	N
P.38	0.1	Y	N	NA	N
P.39	0.1	Y	N	NA	N
P.40	0.1	Y	N	NA	N
P.41	0.1	Y	N	NA	N
P.42	0.1	Y	N	NA	N
P.43	0.1	Y	N	NA	N
P.44	0.1	Y	N	NA	N
P.45	0.1	Y	N	NA	N
P.46	0.1	Y	N	NA	N
P.47	0.1	Y	N	NA	N
P.48	0.1	Y	N	NA	N
P.49	0.1	Y	N	NA	N
P.50	0.1	Y	N	NA	N
P.51	0.1	Y	N	NA	N
P.52	0.1	Y	N	NA	N
P.53	0.1	Y	N	NA	N
P.54	0.1	Y	N	NA	N
P.55	0.1	Y	N	NA	N
P.56	0.1	Y	N	NA	N
P.57	0.1	Y	N	NA	N
Q. Unknown					
Q.1	0.52	?	?	?	?
Q.2	NR	?	?	?	?

DRAFT REVISED Table 2

Results of Exposure Pathway and Route Assessment for Pigments Red 144/214 and the Associated tPCBs Contained in Industrial and Consumer End Use Products

Code	Maximum Concentration in Product (ppm tPCBs)	Criterion I (exposure possible?)	Criterion II		Proceed with HHRA?
			A (10 ppm)	B (1 ppm)	
Q.3	NR	?	?	?	?
R. Glue					
R.1	0.01	Y	N	NA	N
S. Industrial Conveyor Belts					
S.1	0.8	Y	N	NA	N

NR-Not reported in database; NA-Not applicable; HHRA-Human health risk assessment, [1]Out of business, [2]Recycling of plastics into unknown products, [3]Client refused to provide information, ?-Assessment not possible due to data gap

Mike.Teague@clariant.com
06/17/2005 04:27 PM

To Kimberly Tisa/R1/USEPA/US@EPA
cc John.Paul@clariant.com, Erin.Russell@clariant.com, js1@bbl-inc.com
bcc
Subject Revised Assessment Table

Kim -

You asked yesterday during our call for an estimated submittal date for the recalculation of contaminant in all end uses (basically an update of Table 2 from the August 31, 2004 report using Alta Lab data).

As you know, two separate business divisions supplied pigments to customers, some of which then further processed the material before selling it to the end user. Since the sales data is 1.5 years old, our business people need to go back into our documentation to refamiliarize themselves with the connections between lots sold to customers and contaminant concentrations. The sales trail from the Pigments division is pretty straightforward, and John Paul is having those people look at the lot-level sales information while he's gone next week. The sales trail from the Masterbatches division, although documented, is more complicated and less understandable to a nonbusiness person (in other words, I can't do it without a lot of help). I've made contact with the expert in Masterbatches who did this work for us initially, and he has agreed to work on the Masterbatch product calculations while I'm out next week. I'm assuming these people can get results back to me within one week, but that's a guess.

Once I get the new data, I still have to match them up with the customer let-down data, recalculate the end product concentrations and then pass all that information on to BBL for final sign-off as to the need or not for further assessment. Since I'm travelling on business the first part of the week of the 27th, I won't be able to begin this task in earnest until June 30. Therefore, I'm going to say I can have the revised table to you no later than July 8 (we've got the 4th holiday in that week too). I know that probably seems like a long time just to rework a table, but please understand this isn't a trivial exercise and that we're trying to provide you with the most reliable data we can given the circumstances of our schedules. I'll certainly send it earlier if at all possible.

As agreed, we need to keep the carpet assessment moving along with BBL in my absence. John Schell sent his contact information to you separately, so please copy him on Versar's instructions next week.

Thanks.

Mike

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